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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,013	04/24/2000	HIROYUKI SHIMIZU	32-254P	7526

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,013	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

12, 13

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6 ^{12, 13} is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment received 3/18/04 has been entered and claims 1, 3-6, 12, 13 are currently pending in this application.

In view of the amendments to the claims, the rejection of record under 35 USC 112, second paragraph, is hereby withdrawn.

The claims are directed to a method for inhibiting the degradation of peptides, to any degree because no results are claimed, by placing the peptides in a container made of silicone or plastic. This is anticipated by placing such peptides in any container made of silicone or plastic with any result. Claim 5 specifies no aprotinin is added to the container. The arguments presented focus on the absence of any degradation inhibiting agents.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Lindberg and Clerico.

Lindberg (Pharmacology & Tox) entitled "Adsorption of Atrial Natriuretic Peptide to Different Materials" teaches on page 278 column 2 first full paragraph, loss of recovery of ANP at different concentrations in different containers was determined

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where the containers include siliconized glass and coated polymers including polystyrene. See page 278 Fig. 4 which shows siliconized glass, polypropylene, glass, polystyrene, and polyethylene containers. On page 279, Fig. 5 shows ANP in solutions with and without degradation inhibiting compounds.

Clerico (Clin Chem) entitled "Analytical Performance and Clinical Usefulness of a Commercially Available IRMA Kit for Measuring Atrial Natriuretic Peptide in Patients With Heart Failure" teaches on page 1631 column 2 last paragraph, storage of ANP degrades it. On page 1628 column 1 polypropylene tubes were used for storage. On page 1629 first column, ANP was added with or without plasma protease inhibitors (EDTA and aprotinin) and tested for degradation.

All the features of the claims are taught by each of the above references for the same function as claimed.

Applicant's arguments filed 3/18/04 have been fully considered but they are not persuasive.

Applicants argue that in the present invention, addition of protease inhibitors are not necessary. Glass can activate proteases. The selection of the appropriate container is more important than the addition of a protease inhibitor to the stability of BNP. The cited references require inhibiting agents to be added to the specimen. Lindberg uses purified ANP which contain no proteases. Clerico requires aprotinin for inhibiting the degradation of ANP.

It is the examiner's position that present claims 1, 3, 6, 12 and 13 do not exclude the addition of any inhibiting agents and claim 5 excludes only aprotinin. It is particularly noted that the claims have been amended from closed end "consisting of" terminology to open end "comprising" terminology. The claims do not specify any amount of inhibiting or purity of BNP. Much of applicants' arguments are centered upon unclaimed limitations, such as presence or absence of inhibiting agents and the purity of the sample. It is respectfully submitted that in order for evidence of unexpected results to be sufficient to rebut a prima facie case of obviousness, the evidence must be commensurate in scope with the claims.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The Abstract of the Disclosure is objected to because of legal phraseology. Correction is required. See M.P.E.P. § 608.01(b).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

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